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10/631,029	07/29/2003	Rajinder Singh	28575/US/US	3056

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,029	SINGH ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 42-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26, 28-33, 35-40 and 42-48* is/are rejected.

7)☐ Claim(s) *27 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/22/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-40 AND 42-48 ARE PRESENTED FOR EXAMINATION

Applicants' amendment and Information Disclosure Statement filed February 22, 2006 have been received and entered into the application. Accordingly, claims 1, 8, 10, 25, 29, 40, 42 and 43 have been amended and claim 41 has been canceled. Also, as reflected by the attached, completed copy of "Substitute for form 1449A/PTO", (1 sheet), the references cited by Applicants have been considered.

In view of the above amendments, in particular to claim 1, the rejection of claims 1-48 under 35 U.S.C. § 112, first paragraph, as set forth in the previous Office action dated August 22, 2005, has been overcome and thus is now *withdrawn*. Also, in light of the comments regarding Davis et al., (U.S. Patent No. 5,958,935), (see pages 21-23 of the amendment), the rejection of claims 1-48 under 35 U.S.C. § 102(b) as being anticipated by Davis et al. is *withdrawn*.

Also, in light of the comments at pages 19-21 respecting the construction, i.e., wording, of the previously set forth rejections, the provisional obviousness-type double patenting rejections set forth in the previous Office action are *withdrawn*. Further even if the construction of the previous provisional rejections were proper, upon reconsideration of this issue, it is not believed that such a rejection would now be proper. In particular, the presently claimed methods of treating autoimmune diseases would not have been obvious from the claims of the co-pending applications. i.e., Serial Nos. 10/858,343 and 10/355,543. This is believed to be so because even though the present and co-pending claims define the same or similar compounds, there is no teaching or suggestion in the co-pending claims that the compounds could or should be employed for treating an autoimmune disease. In reaching this conclusion, the Examiner has

employed the one-way test of obviousness set forth in MPEP § 804.B.1.(a). In particular, "If the application at issue is the later filed application or both are filed on the same day, only a one-way determination of obviousness is needed in resolving the issue of double patenting, i.e., whether the invention defined in a claim in the application *>would have been< an obvious variation of the invention defined in a claim in the patent.".

Further, such a rejection, provisional or not, would not appear to be proper given that in the '543 application, a restriction requirement was made wherein it was indicated that the compounds of the application were patentably distinct from methods of treating diseases with such compounds, (see the Office action dated June 16, 2004). Similarly, in the '343 application in a restriction requirement dated April 27, 2005, it was determined that the compounds claimed therein were patentably distinct from a method which involved the administration of such compounds to a host in order to achieve a therapeutic objective, i.e., for inhibiting degranulation of mast and/or basophil cells. The present claims similarly define a method of administering the compounds to a host in order to achieve a therapeutic method, i.e., treating autoimmune diseases. Given such similarity, it is believed reasonable to find that the conclusion of patentable distinctness would extend to the present claims thus rendering a finding of obviousness-type double patenting improper, (see MPEP § 804.01).

Claim Objection

Claims 27 and 34 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claims 1-9, 14, 16-20, 32, 35-37, 40, 42, 43, 45 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Pease et al., (WO 01/64656, cited at page 3 of Applicants' IDS filed January 7, 2004).

Pease et al. disclose Applicants' claimed 2,4-pyrimidinediamine compounds, (pages 31-43, Examples 1-41), as being effective in a method for treating autoimmune diseases and rheumatoid arthritis, (page 2, lines 6-7 and 8), which comprises administering a pharmaceutical composition, which may comprise the 2,4-pyrimidinediamine compound as well as a pharmaceutically acceptable diluent or carrier (page 26, lines 15-22 and 25-32).

The teaching of autoimmune diseases is deemed to represent a genus sufficiently small so as to have placed the subject matter of present claim 43, (i.e., directed to sub-genus types of autoimmune diseases, such as autoimmune diseases that are frequently designated as single organ or single cell-type autoimmune disorders).

II Claims 1-11, 12-26, 28, 35, 36, 40, 42, 43 and 45-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Armistead et al., (WO 01/60816, cited at page 4 of Applicants' IDS filed January 7, 2004).

Armistead et al. disclose Applicants' claimed 2,4-pyrimidinediamine compounds, (page 25, Table 1, compounds 1, 3, 5-10; page 28, compounds 35-37; page 29, compounds 43 and 44; and page 30, compounds 54 and 56-60), as being effective in a method for treating "autoimmunological" diseases, (i.e., autoimmune diseases from the plain meaning of the words of the reference at page 21, line 13), including rheumatoid arthritis, multiple sclerosis and lupus (page 21, lines 20-22), which comprises administering a pharmaceutical composition, which may comprise the 2,4-pyrimidinediamine compound as well as a pharmaceutically acceptable diluent or carrier (pages 40-43).

The teaching of autoimmune diseases is deemed to represent a genus sufficiently small so as to have placed the subject matter of present claim 43, (i.e., directed to sub-genus types of autoimmune diseases, such as autoimmune diseases that are frequently designated as single organ or single cell-type autoimmune disorders).

III Claims 1-9, 14-26, 29, 28-33, 35-40, 42, 43, 45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Bradbury et al., (WO 01/39101, cited at page 4 of Applicants' IDS filed January 7, 2004).

Bradbury et al. disclose Applicants' claimed 2,4-pyrimidinediamine compounds, (see examples on pages 55, 56, 62, 63, 70, 82-85, 87-92, 94, 97, 99, 100 and 103), as being effective in a method for treating autoimmune diseases and rheumatoid arthritis, (page 52, lines 10 and 11), which comprises administering a pharmaceutical composition, which may comprise the 2,4-pyrimidinediamine compound as well as a pharmaceutically acceptable diluent or carrier (page 50, line 20 – page 51, line 10 and page 52, line 29 – page 53, line 1;).

The teaching of autoimmune diseases is deemed to represent a genus sufficiently small so as to have placed the subject matter of present claim 43, (i.e., directed to sub-genus types of autoimmune diseases, such as autoimmune diseases that are frequently designated as single organ or single cell-type autoimmune disorders).

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26, 28-33, 35-40 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Pease et al., (WO 01/64656, cited at page 3 of Applicants' IDS filed January 7, 2004), Armistead et al., (WO 01/60816, cited at page 4 of Applicants' IDS filed January 7, 2004) or Bradbury et al., (WO 01/39101, cited at page 4 of Applicants' IDS filed January 7, 2004), for the reasons above, which reasons are here incorporated by reference.

The difference between the above and the claimed subject matter lies in that none of the references teach the specific, presently claimed autoimmune diseases/disorders as in present claims 44 and 45).

However, the difference between the subject matter sought to be patented and the prior art is such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because each of the references makes clear that autoimmune diseases/disorders are amenable to treatment and one of ordinary skill in the art in practicing the methods taught by any of the references would have been motivated to identify and to treat any specific autoimmune disease/disorder known to him/her in order to realize the benefits as taught by any of the references, i.e., that autoimmune diseases/disorders may be effectively treated.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

September 26, 2006